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March 2, 2007
March 9, 2007 (Public Version)

BY E-FILE

PUBLIC VERSION

The Honorable Gregory M. Sleet
United States District Court
U.S. Courthouse
844 North King Street
Wilmington, DE 19801

Re: Talecris Biotherapeutics, Inc. v. Baxter International Inc. and Baxter
Healthcare Corporation, D. Del., C.A. No. 05-349-GMS

Dear Judge Sleet:

Pursuant to Delaware Local Rule 7.1.2(c), Baxter respectfully calls the Court's attention to a recent Federal Circuit decision, *Cargill, Inc., v. Canbra Foods, Ltd.*, ___ F.3d ___, 2007 U.S. App. LEXIS 3222 (Fed. Cir. Feb. 14, 2007) (opinion by Jordan, J.),¹ that is highly relevant to Baxter's pending Motion For Leave To File An Amended Answer and Counterclaim filed on November 1, 2006 (Docket No. 166). The *Cargill* decision was decided after the final brief was filed pertaining to Baxter's Motion to add an inequitable conduct counterclaim, so could not be provided to the Court in the regular briefing process.

In *Cargill*, the Federal Circuit affirmed a finding of inequitable conduct based on the applicant's failure to disclose to the Patent Office internal test data while disclosing more favorable data. The withheld data undercut representations made by the applicant to overcome numerous rejections from the patent examiner. *Id.* at *11-13. The Federal Circuit found that the applicant should have known the withheld data was material "when the examiner repeatedly raises an issue to which the information relates." *Id.* at *16; *see also id.* at *13-14. Moreover, the repeated omission created a strong inference of the requisite intent to deceive. *Id.* at *16. The Federal Circuit dismissed the patentee's mitigating "good faith" explanations for non-disclosure in light of the materiality of the omission and that "[c]lose cases should be resolved by disclosure, not unilaterally by the applicant." *Id.* at *19-20 (citation omitted). Indeed, the

¹ Judge Jordan was sitting by designation on the Federal Circuit.

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Federal Circuit declared: "self-serving manipulations of highly material evidence can hardly be called 'good faith.'" *Id.* at *20.

REDACTED

Based on the similarities between the *Cargill* case and the instant matter, Baxter respectfully submits that the *Cargill* case should be considered in connection with Baxter's Motion For Leave To File An Amended Answer and Counterclaim. Attached is a copy of the decision for the Court's consideration.

Respectfully,

/s/ Philip A. Rovner

Philip A. Rovner
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PAR/mes/782589

Enclosure

cc: Jeffrey B. Bove, Esq. (by e-mail and hand delivery)
Bradford J. Badke, Esq. (by email and Federal Express)

EXHIBIT A

LEXSEE 2007 U.S. APP. LEXIS 3222



Analysis

As of: Feb 26, 2007

**CARGILL, INCORPORATED, Plaintiff-Appellant, v. CANBRA FOODS, LTD.,
DOW AGROSCIENCES, LLC, and DOW AGROSCIENCES CANADA, INC., De-
fendants-Cross Appellants.**

2006-1265, 2006-1302

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007 U.S. App. LEXIS 3222

February 14, 2007, Decided

PRIOR HISTORY: [*1] Appealed from: United States District Court for the District of Oregon Judge Michael W. Mosman. *Cargill, Inc. v. Canbra Foods, Ltd.*, 2005 U.S. Dist. LEXIS 39164 (D. Or., Dec. 20, 2005)

DISPOSITION: AFFIRMED.

COUNSEL: Allen M. Sokal, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiff-appellant. With him on the brief was Jeffrey W. Abraham.

Harry J. Roper, Jenner & Block LLP, of Chicago, Illinois, argued for defendants-cross appellants. With him on the brief were George S. Bosy, Raymond N. Nimrod, Patrick L. Patras, and Steven McMahon Zeller. Of counsel was Marc Goldman, of Washington, DC. Of counsel on the brief were Guy A. Relford and Kenneth B. Ludwig, Dow AgroSciences LLC, of Indianapolis, Indiana.

JUDGES: Before LINN, PROST, and JORDAN,* Circuit Judges.

* Honorable Kent A. Jordan, Circuit Judge, United States Court of Appeals for the Third Circuit, sitting by designation.

OPINION BY: JORDAN

OPINION: JORDAN, Circuit Judge.

Plaintiff Cargill, Incorporated ("Cargill") appeals from a final judgment of the United States District Court for the District of Oregon concerning four patents owned by Cargill, namely U.S. Patents No. 5,969,169 (the "'169 patent"), No. 6,201,145 (the "'145 patent"), No. 6,270,828 (the "'828 patent"), and [*2] No. 6,680,396 (the "'396 patent"). Upon a motion for summary judgment by Canbra Foods, Ltd., Dow Agrosciences, LLC, and Dow Agrosciences Canada, Inc. (collectively, "Defendants"), the district court held that the '828 and '396 patents are invalid because of the on-sale bar set forth in 35 U.S.C. § 102(b). The court also granted Cargill's motion for summary judgment that Defendants had infringed the '169 and '145 patents. Following trial, however, the court entered judgment that the '169 and '145 patents are unenforceable due to inequitable conduct. Defendants cross-appeal the district court's claim construction with respect to all four patents, as well as its grant of summary judgment of infringement of the '169 and '145 patents.

For the reasons discussed below, we affirm the judgment of the district court with respect to invalidity and unenforceability, and, as a result, Defendants' cross-appeal is moot.

I. BACKGROUND

In the present action, Cargill alleged that Defendants infringed the '169, '145, '828, and '396 patents. The '169 and '145 patents relate to a non-hydrogenated canola oil that possesses superior oxidative stability and fry stability, and is useful [*3] for food applications. The claimed oil is referred to in the '169 and '145 patents by the designation "IMC 130." According to the patents, ordinary canola oil

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is unstable and easily oxidized during cooking, which creates an off-flavor in the food. It also develops an undesirable odor when being stored. Therefore, the superior stability of the IMC 130 oil makes that oil more acceptable for cooking and storage.

The oxidative stability of canola oil can be measured in at least two ways: in terms of AOM (Active Oxygen Method) hours, or in terms of peroxide and para-anisidine values. n1 Generic commercial canola oil typically has an oxidative stability of about 22 AOM hours, whereas IMC 130 has an oxidative stability of about 35 to 40 AOM hours. Claim 1 of the '169 patent therefore recites:

A non-hydrogenated canola oil having a polyunsaturated fatty acid content of from about 7% to about 17%, an oleic acid content of about 74% to about 80% and an oxidative stability of from about 35 to about 40 AOM hours in the absence of added antioxidants.

The '145 patent recites the same oxidative stability range, 35 to 40 AOM hours, in dependent claim 2.

n1 The oxidation of canola oil produces hydroperoxides and aldehydes. Under the Active Oxygen Method, oxidative stability is measured by the number of hours it takes for the oil to reach a peroxide value of 100. Alternatively, oxidative stability can be measured by using a Schaal oven test to determine the increase in the peroxide value, which represents the development of hydroperoxides in the oil, and the para-anisidine value, which represents the development of aldehydes in the oil, over a certain period of time.

[*4]

U.S. Patent Application No. 08/425,108 (the "'108 application"), which ultimately issued as the '169 patent, was initially rejected by the examiner as being anticipated by a European patent application by Wong et al. ("Wong"). The examiner's reasoning was that Wong disclosed a canola oil with a fatty acid composition similar to that of IMC 130. According to the examiner, oxidative stability is based directly on fatty acid composition, and therefore, both the oil disclosed in Wong and IMC 130 would exhibit a similar oxidative stability. In response, the applicant argued that the test data set forth in the specification refutes the examiner's position. The applicant contended that the data demonstrates that two canola oils with similar fatty acid compositions, the claimed IMC 130 oil and an oil designated as IMC 129, have strikingly dif-

ferent oxidative stability values. Thus, the applicant took the position that Wong could not be found to anticipate the claimed oil solely because it recites a canola oil with a similar fatty acid composition.

After several office actions and responses, the examiner allowed the claims and explained that:

IMC 129, which is one of the parent lines [*5] used to produce the instant oil [IMC 130], reads on the fatty acid content but as shown in the examples, does not display the required oxidative stability. As shown in the examples, one cannot predict the oxidative stability of an oil based on the fatty acid composition of the oil.

The '145 patent issued from a continuation of the '108 application, and has the same specification as the '169 patent.

The other two patents at issue, the '828 and '396 patents, relate to canola oil that has low glucosinolate content and low [alpha]-linolenic acid content. According to those patents, reducing the glucosinolate and [alpha]-linolenic acid content results in an oil with desirable properties, including low sulfur content, improved sensory characteristics, and greater oxidative stability. Claim 1 of the '828 patent recites:

A canola oil from Brassica seeds, said oil having an [alpha]-linolenic acid content of about 1.7% to about 7% relative to the total fatty acid content, and a sulfur content of less than or equal to 3.0 ppm as determined by high performance liquid chromatography.

The '396 patent is a continuation of the application that issued as the [*6] '828 patent. Both patents refer to the claimed oil by the designation "IMC 01."

As previously noted, the district court held on summary judgment that the '828 and '396 patents are invalid under the on-sale bar of 35 U.S.C. § 102(b), finding that the invention, IMC 01, was reduced to practice and the subject of a sale prior to the critical date. Also, on summary judgment, the court held that Defendants' product infringed claims 1, 6, and 7 of the '169 patent, and claims 5, 6, and 8 of the '145 patent. However, several issues relating to the '169 and '145 patents remained for trial, including validity, damages, and inequitable conduct. Following trial, the district court granted Defendants'

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motion for judgment that the '169 and '145 patents are unenforceable due to inequitable conduct. In reaching that decision, the court relied on two documents that contained the applicant's internal testing data but that were not disclosed to the examiner during prosecution. Cargill appeals the district court's decisions on invalidity and unenforceability. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

Cargill appeals the district [*7] court's determination that the '169 and '145 patents are unenforceable because of inequitable conduct, and the decision that the '828 and '396 patents are invalid due to the on-sale bar. We address those contentions in turn.

A. Inequitable Conduct

To hold a patent unenforceable due to inequitable conduct, there must be clear and convincing evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the U.S. Patent and Trademark Office ("PTO"). *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006).

The materiality element of inequitable conduct was recently clarified in *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309 (Fed. Cir. 2006). In that decision, we explained that the standard for materiality set forth in the current version of PTO Rule 56, see 37 C.F.R. § 1.56(b)(2006), did not supplant the earlier "reasonable examiner" standard, see 37 C.F.R. § 1.56(a) (1991). *Digital Control*, 437 F.3d at 1316; [*8] see also *Impax Labs.*, 468 F.3d at 1374. Rather, "if a misstatement or omission is material under the new Rule 56, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard. . . it is also material." *Digital Control*, 437 F.3d at 1316. The present version of Rule 56 states that:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels

a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted [*9] in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2006). Under the earlier "reasonable examiner" standard, "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a) (1991).

The intent element of inequitable conduct requires that "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Impax Labs.*, 468 F.3d at 1374-75 (quoting *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). Intent rarely can be, and need not be, proven by direct evidence. *Id.* at 1375. Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue. *Id.*

If a district court finds that the requirements of materiality and intent have been established by clear and convincing evidence, it must then "balance the equities to [*10] determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable." *Id.* (quoting *Monsanto Co. v. Bayer Bio-science N.V.*, 363 F.3d 1235, 1239 (Fed. Cir. 2004)). Under the balancing test, "[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997).

We review the district court's findings on the threshold issues of materiality and intent for clear error. *Impax Labs.*, 468 F.3d at 1375. Accordingly, the district court's determination will be reversed only if there is a "definite and firm conviction" that a mistake has been made." *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003) (quoting *Molins PLC v. Tectron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). We review the ultimate decision regarding inequitable conduct for abuse of discretion. *Impax Labs.*, 468 F.3d at 1375. "An abuse of discretion occurs when (1) the court's decision [*11] is clearly unreasonable, arbitrary, or fanciful, (2) the court's decision is based on an erroneous construction of the law, (3) the court's factual findings are

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clearly erroneous, or (4) the record contains no evidence upon which the court rationally could have based its decision." *Id.*

1. Materiality

In the present case, the district court found that the applicant failed to disclose during prosecution of the '169 and '145 patents two documents containing material information: a 1992 chemistry research report (the "Report") and certain Schaal oven data (the "Oven Data"). As is evident from the portion of the prosecution history quoted earlier, the applicant overcame the examiner's rejection by arguing that IMC 130 oil demonstrated an oxidative stability of 35 to 40 AOM hours, and that those stability values are strikingly superior to IMC 129 oil. However, the Report contains test data indicating that three samples of IMC 129 oil exhibited oxidative stabilities of 32, 35, and 32 AOM hours, which is a range similar to and, at one point, overlapping that of IMC 130. In addition, the Oven Data shows peroxide and para-anisidine values for IMC 129 that appear to be superior to those [*12] of IMC 130. n2

n2 The Oven Data document shows a peroxide value of 10.6 for IMC 129 and 12.7 for IMC 130, and a para-anisidine value of 3.2 for IMC 129 and 3.9 for IMC 130. During prosecution of the '169 patent, the applicant argued that lower peroxide and para-anisidine values indicate greater oxidative stability. The Oven Data appears to show that IMC 129 had lower peroxide and para-anisidine values than IMC 130, which indicates that IMC 129 has a superior oxidative stability. That is in direct contrast with Tables 7 and 8 in the specification of the '169 patent, which show that IMC 130 had lower peroxide and para-anisidine values than IMC 129.

Although the district court did not explicitly reference the "reasonable examiner" standard for materiality, it effectively applied that standard in finding that, by not disclosing those two documents, the applicant "unilaterally withheld information that unquestionably would have been viewed as worthy of serious consideration by the PTO, and might have resulted in the patents not being issued." *Cargill, Inc. v. Canbra Foods, Ltd.*, No. CV03-1209-MO, 2005 U.S. Dist. LEXIS 39164, 2005 WL 3478178, at *2 (D. Ore. Dec. 20, 2005). That finding [*13] is not clearly erroneous. The undisclosed documents contain test data demonstrating that the oxidative stability of IMC 130 is similar to that of IMC 129. Given that a crucial issue during prosecution was whether IMC 130 possessed strikingly superior oxidative stability, it is quite certain that a "reasonable examiner" would consider

such test data to be important in deciding whether to allow the patents to issue. n3

n3 Cargill argues that the district court applied an incorrect standard for materiality under the new Rule 56 when it stated that the applicant's explanations for the apparent inconsistency were not "obvious and non-debatable." The district court's opinion shows that it endeavored to apply this court's standards with fidelity, and we therefore do not agree with Cargill that a novel and flawed approach to materiality was applied. In any event, because we conclude that the withheld documents are plainly material under the "reasonable examiner" standard, we need not further address Cargill's contention.

Cargill argues that the data contained in the 1992 Report is not material because the tests underlying the Report were performed under unusual conditions [*14] and, thus, are not comparable to the data submitted to the examiner. For example, according to Cargill, the Report involved the testing of bench-refined IMC 129 oil, which has an inherently higher oxidative stability than pilot-plant and commercially refined oil. Cargill also contends that, because the Oven Data does not set forth any testing conditions, it too cannot be compared with the data before the examiner.

Even accepting as true the factual premises of those arguments, the documents withheld during prosecution remain material. "[M]ateriality is determined from the viewpoint of a reasonable patent examiner, and not the subjective beliefs of the patentee." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1238 (Fed. Cir. 2003) (internal citations omitted). A reasonable examiner would certainly want to consider test data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data. Whether the examiner would have ultimately allowed the patent to issue is irrelevant because "[u]nder the 'reasonable examiner' standard, a misstatement or omission may be material even if disclosure [*15] of that misstatement or omission would not have rendered the invention unpatentable." *Digital Control*, 437 F.3d at 1318. Therefore, the district court's decision regarding the materiality of the undisclosed documents is not clearly erroneous.

2. Intent

The district court found an intent to deceive based on several circumstantial factors: the repeated nature of the omission, the applicant's motive to conceal, and the high materiality of the undisclosed information. With respect to the first factor, the court found that there were multiple occasions that called for disclosure of the omitted data.

The district court did not elaborate on the importance of that factor, and, as a result, Cargill questions its significance. The repeated omission, however, is relevant because "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." *Critikon*, 120 F.3d at 1256. An applicant should know information is material when the examiner repeatedly raises an issue to which the information relates. In *Critikon*, a factor in our finding of intent was [*16] that the examiner reiterated, on at least two occasions, the importance of a specific point of novelty in the application. *Id.* We concluded that the applicant should have known that any information related to that point of novelty would be material to the examiner. *Id.* In this case, each of the examiner's five rejections involved the issue of whether the oxidative stability of IMC 130 was superior to that of oil with a similar fatty acid composition. The repeated nature of that rejection demonstrates that the applicant should have been aware of the materiality of the omitted test data, and, therefore, the district court properly considered it as significant circumstantial evidence of an intent to deceive the PTO about the evidence relevant to the application.

The district court also based its finding of intent on the applicant's motive to deceive the PTO. Cargill contends that an applicant's motive to obtain a patent is insufficient grounds for inferring an intent to deceive. That argument, however, whether sound or not, is not pertinent to this case because the district court did not rely solely on the applicant's motive in drawing an inference of intent. The court's opinion [*17] addressed three circumstantial factors, motive being only one of them. Furthermore, in its discussion of motive, the district court was not referring to some general desire to obtain a patent. The court explained the applicant's specific motive to conceal the two specific documents at issue in this case:

[P]roducing a better, longer lasting strain of oil, one that would be more attractive to customers, would not have gotten Cargill a patent. A patent required something more than an incremental improvement. But the omitted data stood in the way of portraying IMC 130 as something more than an incremental improvement.

There is no error either in that observation or in the district court's relying on it as part of the basis for finding intent.

The district court found the high degree of materiality of the undisclosed test data to be the most potent evidence of intent. The court explained that, "[m]ore than anything

else, it is the omitted data's high degree of relevance that points toward an intent to conceal it from the PTO." Cargill challenges the court's reasoning on the ground that "[i]ntent to deceive cannot be inferred simply from the decision to withhold the [*18] reference where the reasons given for the withholding are plausible." We need not assess whether that proposition accurately states the law because, once more, the argument is inapposite. The district court did not rely simply on the applicant's decision to withhold the information. It relied on an assessment of all the evidence, which included an analysis of the particular materiality of the withheld information. We have never held that materiality is irrelevant to the question of intent. To the contrary, we have recognized that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead." *Critikon*, 120 F.3d at 1257. Here, the district court found that the omitted test data was related to "the heart of the question that bedeviled the examiner: the nature of the difference between IMC 129 and IMC 130." Such a high degree of materiality, coupled with evidence that the applicant should have known of that materiality, creates a strong inference of an intent to deceive.

Cargill [*19] argues that any inference of intent is negated by the district court's finding that the applicant had a good faith belief that the withheld test data did not need to be disclosed to the examiner. That assertion misreads the district court's factual determination about the applicant's state of mind. While gently suggesting that the applicant perhaps honestly believed IMC 130 to be a patentable invention, the court nevertheless expressly held that the applicant knowingly misled the PTO about the available evidence. Even if there were a mitigating explanation for the withheld data, it was no excuse for the applicant's purposeful omissions in this case. "Close cases should be resolved by disclosure, not unilaterally by the applicant." *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992). That rule is drawn from the policy that "applicants [should] continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality." *Critikon*, 120 F.3d at 1257.

While we have recognized that subjective good faith can support a defense to inequitable conduct, [*20] see *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1095 (Fed. Cir. 1987) ("To the extent that Browning is arguing that . . . subjective good faith is never a defense to a claim of inequitable conduct, we rejected that contention . . .") (internal quotations omitted), there is no such thing as a good faith intent to deceive. When an applicant

knows or obviously should know that information would be material to the examiner, as was true here, but the applicant decides to withhold that information, "good faith" does not negate an intent to manipulate the evidence. n4 Indeed, self-serving manipulation of highly material evidence can hardly be called "good faith." Cf. *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F.2d 292, 294 (Fed. Cir. 1986) (explaining that, in *Argus Chemical Corp. v. Fibre Glass-Evercoat Co.*, 759 F.2d 10 (Fed. Cir. 1985), good faith did not negate inequitable conduct because the withheld information "was known by counsel and counsel should have known that it was material to the examiner"). Therefore, we hold that the district court's finding of an intent to deceive was not clearly erroneous.

n4 The district court found that Defendants had met their burden of proof with respect to the applicant's knowledge of the Oven Data because "[t]he document containing the data bore [the] name [of the applicant's head of R&D], which he admitted would indicate it was his copy." Cargill contends that his name appeared on one page containing flavor stability data, and not oxidative stability data. Cargill is correct with respect to that limited assertion. But the consecutive handwritten numbers in the upper right-hand corner of each page indicate that all of the test results are part of a single report. Since the name of the applicant's head of R&D appears on the first page of that document, the district court did not err in concluding that he had knowledge of all the test data contained in that report.

[*21]

3. Balancing

After finding that the elements of materiality and intent had been established by clear and convincing evidence, the district court evaluated all the circumstances of the applicant's conduct and decided that the '169 and '145 patents are unenforceable. In particular, the judge considered Cargill's evidence regarding the rationale for withholding the test data and concluded that, "in light of my own observations of [the applicant's head of R&D] and all the other evidence, I think it highly likely he omitted the information because he concluded it could be explained away." However, the court determined that such evidence did not overcome the weight of evidence proving inequitable conduct. It was within the district court's discretion to weigh its findings of materiality and intent against other evidence, including what Cargill offered as the reasons for withholding highly material information. See *Impax Labs.*, 468 F.3d at 1375. Given the high materiality of the undisclosed information and the strong circumstantial evidence of an intent to mislead, we

cannot say that the court abused its discretion. Accordingly, we affirm the district court's decision [*22] that the '169 and '145 patents are unenforceable.

B. On-Sale Bar

A patent is invalid under the on-sale bar of 35 U.S.C. § 102(b) if, more than one year before the application was filed, two conditions are satisfied: first, the claimed invention must be the subject of a commercial sale or offer for sale, and, second, it must be ready for patenting. *Sparton Corp. v. United States*, 399 F.3d 1321, 1323 (Fed. Cir. 2005). An invention can be found to be "ready for patenting" in at least the following ways: by proof that it was reduced to practice, or by proof that the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention. *Id.*

The district court held, on summary judgment, that the '828 and '396 patents are invalid. We review a district court's grant of summary judgment of invalidity *de novo*. *Medrad, Inc. v. Tyco Healthcare Group LP*, 466 F.3d 1047, 1050 (Fed. Cir. 2006). Summary judgment is only appropriate when there are no genuine issues of material fact, and the movant is entitled to judgment as a matter of law. [*23] See Fed. R. Civ. P. 56(c); *Medrad*, 466 F.3d at 1050.

1. Sale/Offer for Sale

In considering Defendants' motion for summary judgment, the district court focused on a transaction between Cargill's predecessor in interest, DNA Plant Technology Corporation ("DNAP"), and Proctor & Gamble ("P&G"). The court concluded that there was "no real dispute" that the transaction with P&G "was a sale and not a giveaway." That decision was based primarily on a letter sent by Mr. Chan Atchley n5 of DNAP to Mr. John Hunter n6 of P&G on June 7, 1990 (the "June 7 letter"), which reads as follows:

This is to confirm your verbal request for 400 pounds of our low (<3%) alpha linolenic (18:3) RBD canola oil. The oil is scheduled to be shipped from the POS pilot plant in Saskatoon, Canada, October 1, 1990 and should be in your hands by the end of the following week. The oil will be shipped in a 55 gallon plastic container and will cost \$ 1.50 per pound FOB Saskatoon.

The court explained that it could not "find any way to interpret the language linking a buck fifty with FOB to be anything other than a sale." On appeal, Cargill does [*24] not dispute that the June 7 letter involved the canola oil

claimed in the '828 and '396 patents. Nor does Cargill dispute that the June 7 letter was sent before the critical date of September 30, 1990. The issue regarding the first prong of the on-sale bar test thus becomes whether the P&G transaction qualifies as either a sale or an offer for sale.

n5 At the time the letter was sent, Mr. Chan Atchley was the General Manager of Oils at DNAP.

n6 At the time the letter was sent, Mr. John Hunter was in charge of product development at P&G's Miami Valley Laboratories in Ohio.

The material facts are not in dispute on this point. The dispute is over the legal conclusion to be drawn from the facts. The June 7 letter explicitly sets forth an amount of oil to be delivered to P&G, at a specified unit price, and under a standard contract designation, FOB (free on board), which allocates the risks and responsibilities of a buyer and a seller. See Black's Law Dictionary 690 (8th ed. 2004) (defining "free on board"). As recognized by the district court, that is powerful evidence of a sales transaction.

Cargill's position is that DNAP was providing P&G with a sample [*25] of the claimed oil for testing purposes. Cargill attempts to reconcile its position with the price term recited in the June 7 letter by arguing that the \$ 1.50 was actually DNAP's cost of processing the oil. In particular, Cargill asserts that the \$ 1.50 could not be a sales price because it is much higher than the normal price for canola oil, which is \$ 0.20 to \$ 0.40 per pound. Cargill explains that the cost of processing the 400-pound "sample" was so high because it was such a low quantity that it needed to be produced at a pilot plant, and thus could not benefit from economies of scale. Assuming that factual recitation is correct, Cargill's argument only serves to prove the district court's conclusion. If production costs rise for smaller quantities, then \$ 1.50 may indeed be a reasonable sales price for 400 pounds of oil, even though it is much higher than the normal price for much larger quantities.

Cargill also argues that P&G had previously expressed concern about production expenses, and, therefore, it makes sense that DNAP would include cost figures in the June 7 letter. Again, Cargill's explanation is problematic. If the 400 pounds of oil was really a "free sample" so that [*26] P&G could determine whether it wanted to order larger commercial quantities, P&G would not be concerned about the inflated cost of processing the sample at a pilot plant. Rather, P&G would only be interested in the cost of producing the much larger quanti-

ties that it ultimately would be purchasing. Moreover, Cargill never explains the contract delivery terminology "FOB" as anything but the commercial provision it is typically understood to be.

Cargill tries to recast its offer for sale as merely a ramp up to a business relationship, pointing out that the June 7 letter suggested that DNAP wanted "very much to do business" with P&G and that the parties should discuss a purchase agreement. However, expressing a desire to do business in the future does not negate the commercial character of the transaction then under discussion. Cargill also argues that DNAP never invoiced the P&G transaction, and P&G never paid for the 400 pounds of oil. Even if true, evidence of an offer to sell is sufficient to trigger the on-sale bar under 35 U.S.C. § 102(b). There is no requirement that the sale be completed.

Finally, Cargill offers the declaration of Mr. Atchley in which [*27] he explains that DNAP did not view the June 7 letter as an offer for a sale. Since we agree with the district court that the language of the letter itself is unambiguous, we also conclude that the subsequent testimony of Mr. Atchley about the intended purpose of the letter is, for practical purposes, irrelevant. Cargill contends that it has, at least, established a genuine issue of material fact, and that, therefore, the district court should not have granted summary judgment. However, "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986) (original emphasis omitted). Cargill's post hoc effort to say DNAP did not intend what is abundantly plain from the price, quantity, and delivery terms on the face of the June 7 letter does not raise a genuine issue of fact. Furthermore, as already noted, Cargill's explanations for including such terms in the letter actually support the district court's conclusion that the \$ 1.50 figure was what [*28] it appears to be, a sales price in an offer for sale. Accordingly, there is no genuine dispute that the June 7 letter constituted an offer to sell the oil claimed in the '828 and '396 patents.

2. Ready for Patenting

The district court found that the invention disclosed in the '828 and '396 patents was ready for patenting prior to the critical date because there was proof of reduction to practice. More specifically, the court concluded that the claimed oil was reduced to practice because "when it's composed or made, it's reduced to practice." Cargill argues that the district court made an error of law because an invention is only reduced to practice when it is shown to work for its intended purpose. However, the district court's decision is not inconsistent with that statement of

the law. The court based its decision on *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999). In *Abbott Laboratories*, we held that "[t]he fact that the claimed material was sold under circumstances in which no question existed that it was useful means that it was reduced to practice." 182 F.3d at 1318. In this case, the evidence demonstrates [*29] that DNAP was aware of the utility of the claimed oil prior to its offer to sell the oil to P&G on June 7, 1990.

For example, on February 9, 1990, a letter was sent from DNAP to the Biotechnology Director at another company, Du Pont, stating that: "Oil extracted from a one acre grow-out from line 336 seed was analyzed and found to be superior to that of our competitors. The oil is light colored, has good stability in high heat applications and develops no off odors." n7 Furthermore, in a discussion with Mr. Hunter of P&G on March 6, 1990, Mr. Atchley of DNAP n8 noted that the oil performed very well in P&G's fry tests, and that P&G's results were consistent with those DNAP reported. n9

n7 Canola oil grown from the line 336 seed is the canola oil that was the subject of the June 7 letter.

n8 It is not clear from the document itself that the notes were taken by Mr. Atchley. However, Cargill confirms that the document contains Mr. Atchley's notes: "In March 1990, Mr. Atchley and Mr. Hunter again discussed P&G's testing of DNAP's oils. Mr. Hunter reported results from initial fry tests, and Mr. Atchley's notes indicate that DNAP oil [p]erformed very well."

n9 Mr. Atchley's notes do not mention the specific oil being tested by P&G. However, the notes do state that P&G "would want one 55 gal. drum" of the oil, suggesting that Mr. Atchley was discussing the same type of oil on March 6 that DNAP later formally agreed to sell to P&G in that quantity. Furthermore, Cargill does not dispute that Mr. Atchley's notes refer to the same oil as was specified in the June 7 letter.

[*30]

Cargill also contends that the invention could not have been reduced to practice before the June 7 letter

because the district court found that the P&G transaction was for experimental purposes. Although the district court concluded that the transaction was experimental, that does not mean that the invention had not been reduced to practice. In *Abbott Laboratories*, we explained that "[i]t is well settled in the law that there is no requirement that a sales offer specifically identify all the characteristics of an invention offered for sale or that the parties recognize the significance of all of these characteristics at the time of the offer." 182 F.3d at 1319. Since DNAP knew of the general utility of the claimed oil, it was reduced to practice. DNAP did not need to be aware of the specific characteristics that made the oil useful. As a result, even if DNAP offered to sell the oil to P&G for the purpose of continued testing, it does not prevent a finding that the oil had already been reduced to practice. n10 Therefore, we hold that there is no genuine issue of material fact that the oil claimed in '828 and '396 patents was the subject of an offer for sale and was [*31] reduced to practice before the critical date of September 30, 1990.

n10 Because the district court found, and we agree, that the claimed invention was reduced to practice before the June 7 letter, it is irrelevant whether the P&G transaction was for experimental purposes. "[O]nce the invention is reduced to practice, there can be no experimental use negation." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354 (Fed. Cir. 2002).

Accordingly, because the oil claimed in those patents was the subject of at least an offer for sale before the critical date, and because the claimed oil had already been reduced to practice, we affirm the district court's decision that the '828 and '396 patents are invalid under 35 U.S.C. § 102(b).

III. CONCLUSION

For the aforementioned reasons, we affirm the judgment of the district court as to the invalidity of the '828 and '396 patents and as to the unenforceability of the [*32] '169 and '145 patents. The remaining aspects of the appeal are dismissed as moot.

AFFIRMED

COSTS

Each party shall bear its own costs.